

Miracle-Ear®

October 2, 2000

Honorable Donna Shalala
Secretary of Health and Human Services 8 2 3 9 '00 OCT 19 P2:08
200 Independence Avenue, S.W. Room 615F
Washington, D.C. 20201

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707 East Mingus Ave.
Suite 502
Cottonwood, AZ 86326
Phone (520) 634-5122

SEARS

Hearing Aid Centers

Flagstaff Mall
4800 N. Highway 89
Flagstaff, Arizona 86004
Phone (520) 526-6700

Metrocenter Mall
10001 N. Metro Parkway West
Phoenix, Arizona 85051
Phone (602) 870-3311

Fiesta Mall
1425 W. Southern Ave.
Mesa, Arizona 85202
Phone (480) 649-8474

Paradise Valley Mall
4604 E. Cactus
Phoenix, Arizona 85032
Phone (602) 953-1422

Desert Sky Mall
7611 W. Thomas Road
Phoenix, Arizona 85033
Phone (623) 846-8511

Fashion Square Mall
7014 E. Camelback
Suite 5000
Scottsdale, Arizona 85251
Phone (602) 840-0038

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Dear Secretary Shalala:

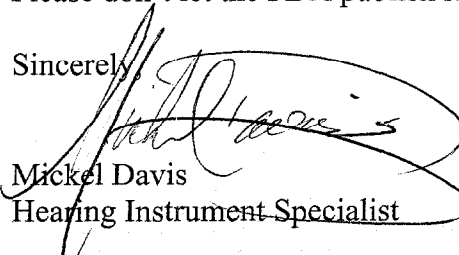
I am a small business person in Arizona, providing hearing health care services to the area's hearing impaired. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing health care and reduce access to hearing health care providers. Please take the time to consider the impact of this proposed hearing aid rule on the nation's hearing-impaired and on the nation's small business hearing health care providers, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Hearing health care providers like me have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new Administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the marketplace. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

As you may have seen, the AARP recently published a *Consumer Guide to Hearing Aids* which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20 percent of those who need a hearing aid have one." Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.

Please don't let the FDA publish its proposed hearing aid rule.

Sincerely,


Mickel Davis

Hearing Instrument Specialist

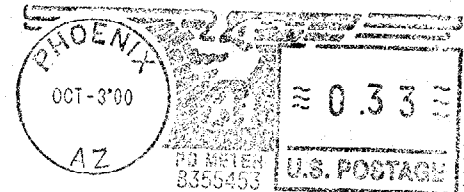
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